IN THE SPECIFICATION:

Please substitute the following paragraphs for the paragraphs identified in the page and line numbers immediately above the paragraph:

Substitute the paragraph on page 1, lines 26-34 with:

Of particular interest to the invention are pulmonary delivery techniques which rely on the inhalation of a pharmaceutical formulation by the patient so that the active drug within the dispersion can reach the distal (alveolar) regions of the lung. A variety of aerosolization systems have been proposed to disperse pharmaceutical formulations. For example, U.S. Pat. Nos. 5,785,049 and 5,740,794, the disclosures of which are herein incorporated by reference, describe exemplary active powder dispersion devices which utilize a compressed gas to aerosolize a powder. Other types of aerosolization systems include MDI's (metered dose inhalers) (which typically have a drug that is stored in a propellant), nebulizers (which aerosolize liquids using compressed gas, usually air), and the like.

Substitute the paragraph on page 2, lines 20-25 with:

Problems associated with variability among patient inspiratory efforts have been addressed through modifications of dry powder inhaler device designs. For example, WO 01/00263 and WO 00/21594, hereby incorporated in their entirety by reference, disclose dry powder inhalers including flow regulation and flow resistance modulation. Examples of other DPIs (dry powder inhalers) are disclosed in U.S. Pat. Nos. 4,995,385 and 5,727,546, herein incorporated in their entirety by reference.

Substitute the paragraph on page 19, line 6 with:

Hollow porous budesonide particles were prepared by a two-step process. In the first step, 54 mg of budesonide (Vinchem, Chatham, N.J.), and 0.775 g of DSPC (distearoylphosphatidylcholine) were dissolved in 2 ml of chloroform:methanol (2:1). The chloroform:methanol was then evaporated to obtain a thin film of the phospholipid/steroid mixture. The phospholipid/steroid mixture was then dispersed in 30.5 g of hot deionized water (T=60 to 70° C.) using an Ultra-Turrax mixer (model T-25) at 8000 rpm for 2 to 5 minutes. 12.8 g of perfluorooctyl ethane was then added dropwise during mixing. After the addition was complete, the emulsion was mixed for an additional period of not less than 4 minutes. The coarse emulsion was then passed through a high pressure homogenizer (Avestin, Ottawa, Canada) at 18,000 psi for 5 passes. The resulting submicron fluorocarbon-in-water with steroid solubilized in the lipid monolayer surrounding the droplets was utilized as the feedstock in for the second step, i.e. spray-drying on a B-191 Mini Spray-Drier (Buichi, Flawil, Switzerland). Calcium chloride (0 or 0.65 mg) was added in 2.5 g of water to the fluorocarbon-in-water emulsion immediately prior to spray drying. The following spray conditions were employed: aspiration=100%, inlet temperature=85° C., outlet temperature=60° C., feed pump=1.9 mL min^{-1}, atomizer pressure=60-65 psig, atomizer flow rate=30-35 cm. The aspiration flow (69-75%) was adjusted to maintain an exhaust bag pressure of 30-31 mbar. Free flowing white powders were collected using a standard cyclone separator.

Substitute Table 1 on page 20, line 3 with the following Table:

Table I

Budesonide Aerosol Characteristics

Device	Resistance	Peak Flow Rate (LPM)	Emitted Dose (%)	Total Dose	MMAD (um)	~~FPD~~ FPF (%<3.3 um)
Eclipse	0.19	20	89	72	3.2	37
				68	3.0	36
		41	94	73	2.0	50
				73	2.3	44
Flowcaps	0.15-.20	23	93	66	4.3	21
				46	3.7	17
		37	102	70	2.6	40
				72	3.0	36
Cipla Rotohaler	0.16	23	96	76	4.0	28
				78	3.9	29
		43	98	74	2.9	42
				86	2.9	47
Turbospin	0.09	24	95	87	3.5	37
				93	3.6	40
		60	96	77	2.4	46
				73	2.3	44
Glaxo Rotohaler	0.04	62	95	73	3.1	36
				72	3.1	36
		90	103	88	3.2	49
				85	3.3	49

Substitute the paragraph on page 22, line 16 with:

A single feed solution is prepared under defined conditions. The feed solution is comprised of leuprolide acetate in the aqueous phase of a fluorocarbon-in-water emulsion. The emulsion composition is listed in Table 3 below. Accordingly, DSPC and calcium chloride dihydrate are dispersed in approximately 400 mL SWFI (sterile water for injection) (T=60-70 C) using an Ultra-Turrax T-50 mixer at 800 rpm for 2 to 5 minutes. The perflubron is then added drop wise during mixing. After the addition is complete, the emulsion is mixed for an additional period of not less than 5 minutes at 10,000 rpm. The resulting coarse emulsion is then homogenized under high pressure with an Avestin C-5 homogenizer (Ottawa, Canada) at 19,000 psi for 5 discrete passes. The emulsion is transferred to the Potent Molecule Laboratory for Leuprolide Acetate addition and spray drying.

Substitute the paragraph on page 21, lines 6-11 with:

The PS_{bud} (PulmoSphere® Nektar Therapeutics made with budesonide) powder was radiolabeled with ^{99m}Tc and deposition determined by gamma scintigraphy. In-vitro experiments confirmed radiolabel acted as a valid marker for drug. Charcoal was administered orally to reduce extra-pulmonary absorption of budesonide, and plasma budesonide concentrations were measured for 12 hour after all treatments. Eight healthy subjects completed the following 3 treatments in a cross-over study:

Substitute the paragraph on page 21, lines 12-19 with:

1. Eclipse Low ~~flow~~ Flow:

PS_{bud} (0.37 mg budesonide) inhaled from the Eclipse DPI at a peak inspiratory flow (PIF) of 29 L/min (SD=3.6)

2. Eclipse High Flow:

PS_{bud} (0.37 mg budesonide) inhaled from the Eclipse DPI at a PIF of 44 L/min (SD=4.2)

3. Turbuhaler:

0.8 mg budesonide inhaled from Turbuhaler at 60 L/min

Substitute the footer paragraph on page 25, lines 25-26 with:

*From_Borgstrom, L. et al. "Lung deposition of budesonide inhaled via Turbohaler ®: a comparison with terbutaline sulphate in normal subjects" Eur Respir. J. 1994, 7, 69-73.

Substitute the title of Table 4 on page 23, 12-13 with:

Flow rate dependence of aerosol properties for a leuprolide ~~Pulmosphere~~ PulmoSphere formulation delivered from the Turbospin DPI device

Substitute the paragraph on page 10, line 15 with:

In addition to the phospholipid, the microparticles of the present invention may also include a biocompatible, preferably biodegradable polymer, copolymer, or blend or other combination thereof. In this respect useful polymers comprise polylactides, polylactide-glycolides, cyclodextrins, polyacrylates, methylcellulose, carboxymethylcellulose, polyvinyl alcohols, polyanhydrides, polylactams, polyvinyl pyrrolidones, polysaccharides (dextrans, starches, chitin, chitosan, ~~etc.~~ and the like), hyaluronic acid, proteins, (albumin, collagen, gelatin, ~~etc.~~ and the like). Examples of polymeric resins that would be useful for the preparation of perforated ink microparticles include: styrene-butadiene, styrene-isoprene, styrene-acrylonitrile, ethylene-vinyl acetate, ethylene-acrylate, ethylene-acrylic acid, ethylene-methylacrylatate, ethylene-ethyl acrylate, vinyl-methyl methacrylate, acrylic acid-methyl methacrylate, and vinyl chloride-vinyl acetate. Those skilled in the art will appreciate that, by selecting the appropriate polymers, the delivery efficiency of the particulate compositions and/or the stability of the dispersions may be tailored to optimize the effectiveness of the active or agent.

Substitute the paragraph on page 10, line 32 to page 11, line 13 with:

Other excipients may include, but are not limited to, carbohydrates including monosaccharides, disaccharides and polysaccharides. For example, monosaccharides such as dextrose (anhydrous and monohydrate), galactose, mannitol, D-mannose, sorbitol, sorbose and the like; disaccharides such as lactose, maltose, sucrose, trehalose, and the like; trisaccharides such as raffinose and the like; and other carbohydrates such as starches (hydroxyethylstarch), cyclodextrins and maltodextrins. Other excipients suitable for use with the present invention, including amino acids, are known in the art such as those disclosed in WO 95/31479, WO 96/32096, and WO 96/32149. Mixtures of carbohydrates and amino acids are further held to be within the scope of the present invention. The inclusion of both inorganic (e.g. sodium chloride, ~~etc.~~ and the like), organic acids and their salts (e.g. carboxylic acids and their salts such as sodium citrate, sodium ascorbate, magnesium gluconate, sodium gluconate, tromethamine hydrochloride, ~~etc.~~ and the like) and buffers is also contemplated. The inclusion of salts and organic solids such as ammonium carbonate, ammonium acetate, ammonium chloride or camphor are also contemplated. According to a preferred embodiment, a metal cation, preferably calcium is added to the feed stock from which the particles are prepared as disclosed in U.S. provisional patent application 60/216,621, previously incorporated by reference.

Substitute the paragraph on page 15, lines 3-10 with:

Although the particulate compositions are preferably formed using a blowing agent as described above, it will be appreciated that, in some instances, no additional blowing agent is required and an aqueous dispersion of the medicament and/or excipients and surfactant(s) are spray dried directly. In such cases, the formulation may be amenable to process conditions (e.g., elevated temperatures) that may lead to the formation of hollow, relatively porous microparticles. Moreover, the medicament may possess special physicochemical properties (e.g., high crystallinity, elevated melting temperature, surface activity, ~~etc.~~ and the like) that makes it particularly suitable for use in such techniques.

Substitute the paragraph on page 17, lines 27-34 with:

Additionally, the particulate compositions of the present invention may also be formed using a double emulsion method. In the double emulsion method the medicament is first dispersed in a polymer dissolved in an organic solvent (e.g. methylene chloride, ethyl acetate) by sonication or homogenization. This primary emulsion is then stabilized by forming a multiple emulsion in a continuous aqueous phase containing an emulsifier such as polyvinylalcohol. Evaporation or extraction using conventional techniques and apparatus then removes the organic solvent. The resulting microspheres are washed, filtered and dried prior to combining them with an appropriate suspension medium in accordance with the present invention.